

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

October 2008 Grand Jury

11	UNITED STATES OF AMERICA,)	No. ED CR 08-172(B) -VAP
12	Plaintiff,)	<u>S E C O N D</u>
13	v.)	<u>S U P E R S E D I N G</u>
14	VINOD CHANDRASHEKM)	<u>I N D I C T M E N T</u>
15	PATWARDHAN,)	[18 U.S.C. § 371: Conspiracy; 21
16	Defendant.)	U.S.C. §§ 331(a), 333(a)(2),
17)	352(c), 352(f)(1): Introducing
18)	Misbranded Drugs into Interstate
19)	Commerce; 18 U.S.C. § 545:
20)	Smuggling Goods into the United
21)	States; 18 U.S.C. §§ 2(a), (b):
)	Causing an Act to be Done; 18
)	U.S.C. § 982(a)(2)(B), 21 U.S.C.
)	§ 853(p): Criminal Forfeiture; 18
)	U.S.C. § 981(a)(1)(C), 28 U.S.C.
)	§ 2461(c), 21 U.S.C. § 853(p):
)	Criminal Forfeiture]
)	
)	

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At all times material to this indictment:

The Food and Drug Administration's Regulation of Drugs

1. The United States Food and Drug Administration ("FDA") is the federal agency within the United States Department of Health and Human Services charged with the responsibility for

1 protecting the health and safety of the American public by
2 enforcing the Federal Food, Drug and Cosmetic Act ("FD&C Act"),
3 21 U.S.C. § 301, et seq. One of the purposes of the FD&C Act is
4 to ensure that all drugs sold for consumption by or
5 administration to humans and animals bear labeling containing
6 only true and accurate information. The FDA's responsibilities
7 under the FD&C Act include regulating the manufacture, labeling,
8 and distribution of all drugs and drug components shipped or
9 received in interstate commerce.

10 2. The FD&C Act defines a "drug" to include, among other
11 things, any article intended for use in the diagnosis, cure,
12 mitigation, treatment, or prevention of disease in humans or
13 other animals; articles (other than food) intended to affect the
14 structure or any function of the body of humans or other animals;
15 and articles intended for use as a component of any such
16 articles.

17 3. The FD&C Act defines "label" as a display of written,
18 printed, or graphic matter upon the immediate container of any
19 article. Any requirement under the FD&C Act that a word,
20 statement, or other information appear on the label shall not be
21 considered to be complied with unless such word, statement, or
22 other information also appears on the outside container or
23 wrapper, if there is any, of the retail package of such article,
24 or is easily legible through the outside container or wrapper.

25 4. The FD&C Act defines "labeling" as all labels and other
26 written, printed, or graphic matters (a) upon any article or any
27 of its containers or wrappers, or (b) accompanying such article.

28 5. A drug is misbranded if, among other things, its

1 labeling (a) does not bear adequate directions for use, or (b) is
2 not likely to be read and understood by the ordinary individual
3 under customary conditions of purchase and use.

4 6. For all drugs distributed in the United States, all
5 words, statements, and other information on the label or labeling
6 required by the FD&C Act must appear in the English language.

7 7. Misbranded drugs can not lawfully be introduced or
8 shipped in interstate commerce.

9 Importation of Drugs Into the United States

10 8. Primary responsibility for administering the laws
11 relating to the importation of goods and merchandise, including
12 drugs, is given to the United States Customs and Border
13 Protection ("CBP"), an agency within the United States Department
14 of Homeland Security ("DHS").

15 9. Federal law requires that all articles brought into the
16 United States by any individual shall be declared to a Customs
17 officer at the port of first arrival in the United States, on a
18 conveyance en route to the United States on which a Customs
19 officer is assigned for that purpose, or at a preclearance office
20 in a foreign country where a United States Customs officer is
21 stationed for that purpose.

22 10. When drugs falling under the jurisdiction of the FDA
23 are declared or offered for import into the United States, CBP
24 notifies the FDA so that the FDA can determine whether sampling
25 of the drug is required and whether importation of the drug is
26 lawful under the FD&C Act.

27 11. All articles offered for import having a value greater
28 than \$2,000.00 are considered by CBP to be formal entries. One

1 requirement for formal entries is the posting of a bond. Under
2 the terms of a formal entry bond, imported articles may be
3 unconditionally released to importers pending a determination of
4 the admissibility and amount of duty to be paid on the articles.
5 The bond requires importers to redeliver the articles to CBP,
6 upon demand of CBP at any time; for example, to allow for FDA
7 sampling or for re-exportation following refusal of admission.

8 12. All articles offered for import having a value less
9 than \$2,000.00 are considered by CBP to be informal entries and
10 do not require posting of a bond. When informal entries that
11 include articles under FDA jurisdiction are to be sampled, or the
12 FDA believes the articles may be in violation of the FD&C Act,
13 the FDA may request that CBP convert the informal entry into a
14 formal entry, which requires the posting of a bond.

15 The Medicare Health Insurance Program

16 13. Medicare is a federal health care benefit program
17 operated by the United States Department of Health and Human
18 Services ("HHS").

19 14. Medicare provides reimbursement for medical care to
20 persons age sixty-five years and older and to certain disabled
21 persons.

22 15. The federal government contracts with private insurance
23 companies, known as Medicare carriers, to administer Medicare.
24 Medicare carriers make payments to authorized health care
25 providers to reimburse them for medical services provided to
26 Medicare beneficiaries, including for drugs administered.

27 16. Medicare requires providers of medical services, such
28 as physicians, to submit claims in order to receive reimbursement

for medical services that they have provided to Medicare beneficiaries. Among other information, providers are required to state on claim forms: (a) the patient's name and Medicare number; (b) the type of service provided (identified by a standardized procedure code number); (c) the date the service was provided; and (d) the provider's name and/or provider number.

Defendant and His Medical Practice

17. Defendant is a medical doctor licensed in the State of California.

18. Defendant operates a medical practice named Patwardhan Medical Administration Services, LLC, which has an office in Upland, California.

19. Defendant specializes in the areas of internal medicine and the treatment of cancer.

20. These introductory allegations are incorporated and re-alleged by reference in each and every count of this Indictment.

COUNT ONE

[18 U.S.C. § 371]

A. OBJECTS OF THE CONSPIRACY

21. Beginning in or before 2005, and continuing to at least on or about July 30, 2008, in San Bernardino County, within the Central District of California, and elsewhere, defendant VINOD CHANDRASHEKM PATWARDHAN, and others known and unknown to the Grand Jury, conspired and agreed with each other to knowingly and intentionally:

a. with intent to defraud and mislead, introduce into interstate commerce drugs that are misbranded, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1);

b. fraudulently and knowingly import and bring merchandise into the United States contrary to law, in violation of 18 U.S.C. § 545;

c. convert, embezzle, steal, and purloin money of HHS, a department or agency of the United States, namely, Medicare reimbursement payments having an aggregate value exceeding \$1,000.00, in violation of 18 U.S.C. § 641; and

d. defraud the United States of and concerning its governmental functions and rights, namely, to interfere with or obstruct the lawful functions of the FDA, HHS, and DHS by deceit, craft, trickery and dishonest means.

1 B. MEANS BY WHICH THE OBJECTS OF THE CONSPIRACY WERE TO BE
2 ACCOMPLISHED

3 22. The objects of the conspiracy were to be accomplished
4 in substance as follows:

5 a. Defendant or a co-conspirator would travel to a
6 foreign country.

7 b. While in the foreign country, defendant or a co-
8 conspirator would pick up or purchase unapproved drugs for use in
9 defendant's medical practice.

10 c. Defendant would pay for the unapproved drugs in
11 one of the following manners: (1) by authorizing a wire transfer
12 from a bank account of his medical practice to the foreign
13 supplier of the unapproved drugs; (2) by arranging for the person
14 traveling to the foreign country to bring a check drawn on a bank
15 account of his medical practice to the foreign country; or (3) by
16 reimbursing the person taking the trip to the foreign country for
17 the cost of the unapproved drugs purchased. If defendant did not
18 personally pick up the unapproved drugs in the foreign country,
19 defendant also would pay for the travel expenses of the person
20 who did pick up the unapproved drugs.

21 d. Defendant or a co-conspirator would return to the
22 United States with the unapproved drugs purchased in the foreign
23 country.

24 e. Upon arrival in the United States, defendant or a
25 co-conspirator would not declare the unapproved drugs purchased
26 in the foreign country on the Customs Declaration form provided
27 by CBP upon return to the United States. Defendant or a co-
28 conspirator would not complete and submit the formal entry

documents required for the importation into the United States of commercial merchandise with a value greater than \$2,000.00 or post a bond as required for such an importation.

f. Defendant or a co-conspirator would transport the unapproved drugs purchased in the foreign country to defendant's medical office in Upland, California.

g. Defendant would administer the unapproved drugs purchased in the foreign country to his patients.

h. To avoid detection by the United States, defendant would never disclose to his patients that he was administering them unapproved drugs. Instead, defendant would identify the unapproved drugs by the name of a drug that was approved by the FDA.

i. To avoid detection by the United States, in communications with other medical professionals who also were providing medical care to his patients, defendant would never disclose that he was administering his patients unapproved drugs. Instead, defendant would identify the unapproved drugs being administered to his patients by the name of a drug approved by the FDA.

j. To avoid detection by the United States, in the medical charts and records of his cancer patients, defendant would never disclose that he was administering them unapproved drugs. Instead, defendant would identify the unapproved drugs being administered by the name of a drug approved by the FDA.

k. For those cancer patients who had health insurance through Medicare, defendant would cause to be submitted to Medicare a fraudulent claim for reimbursement. In particular,

1 defendant would never disclose to Medicare that he was submitting
2 to Medicare claims for reimbursement for the administration of
3 unapproved drugs. Instead, defendant would identify the
4 unapproved drugs for which he was seeking reimbursement by the
5 name of a drug approved by the FDA.

6 C. OVERT ACTS

7 23. In furtherance of the conspiracy and to accomplish the
8 objects of the conspiracy, defendant and others known and unknown
9 to the Grand Jury committed various overt acts within the Central
10 District of California, and elsewhere, including but not limited
11 to the following:

12 OVERT ACT #1: In or about 2005, defendant asked
13 Unindicted Co-Conspirator A to purchase drugs in Canada and bring
14 them back into the United States.

15 OVERT ACT #2: On or about October 28, 2005, defendant
16 traveled from Los Angeles International Airport to Changi,
17 Singapore.

18 OVERT ACT #3: On or about November 5, 2005, after
19 arriving via commercial airliner at Los Angeles International
20 Airport, defendant did not declare to CBP the commercial
21 merchandise in his possession, namely drugs purchased in India.

22 OVERT ACT #4: On or about November 16, 2005, defendant
23 signed wire transfer instructions authorizing a payment of
24 \$24,922.00 to Arihant Chemist, Pune, India for the purchase of
25 drugs brought into the United States from India.

26 OVERT ACT #5: On or about March 30, 2006, defendant
27 traveled from Los Angeles International Airport to Changi,
28 Singapore.

1 OVERT ACT #6: On or about April 8, 2006, after
2 arriving via commercial airliner at Los Angeles International
3 Airport, defendant did not declare to CBP the commercial
4 merchandise in his possession, namely drugs purchased in India.

5 OVERT ACT #7: On or about April 17, 2006, defendant
6 signed wire transfer instructions authorizing a payment of
7 \$49,000.00 to Arihant Chemist, Pune, India for the purchase of
8 drugs brought into the United States from India.

9 OVERT ACT #8: On or about December 28, 2006, defendant
10 traveled from Los Angeles International Airport to Changi,
11 Singapore.

12 OVERT ACT #9: On or about January 3, 2007, after
13 arriving via commercial airliner at Los Angeles International
14 Airport, defendant did not declare to CBP the commercial
15 merchandise in his possession, namely drugs purchased in India.

16 OVERT ACT #10: On or about January 11, 2007, defendant
17 signed wire transfer instructions authorizing a payment of
18 \$53,000.00 to Arihant Chemist, Pune, India for the purchase of
19 drugs brought into the United States from India.

20 OVERT ACT #11: On or about November 14, 2007,
21 Unindicted Co-Conspirator B traveled from Ontario International
22 Airport to Honduras.

23 OVERT ACT #12: On or about November 16, 2007, acting on
24 behalf and at the request of defendant and using funds provided
25 by defendant, Unindicted Co-Conspirator B purchased drugs in
26 Honduras.

27 OVERT ACT #13: On or about November 19, 2007, after
28 arriving via commercial airliner at George Bush

1 Intercontinental/Houston Airport, Unindicted Co-Conspirator B did
2 not declare to CBP the commercial merchandise in her possession,
3 namely drugs purchased in Honduras.

4 OVERT ACT #14: On or about February 12, 2008, defendant
5 directed Unindicted Co-Conspirator B to prepare a check to pay
6 for Unindicted Co-Conspirator C's travel expenses in connection
7 with a planned trip to India.

8 OVERT ACT #15: On or about February 12, 2008,
9 Unindicted Co-Conspirator B prepared a check on defendant's
10 behalf made out to Unindicted Co-Conspirator C.

11 OVERT ACT #16: On or about February 12, 2008, defendant
12 took from Unindicted Co-Conspirator B the check made out to
13 Unindicted Co-Conspirator C.

14 OVERT ACT #17: On or about February 19, 2008,
15 Unindicted Co-Conspirator C traveled to London, England.

16 OVERT ACT #18: On or about March 2, 2008, Unindicted
17 Co-Conspirator C, acting on behalf and at the request of
18 defendant, purchased drugs in India.

19 OVERT ACT #19: On or about March 3, 2008, after
20 arriving via commercial airliner at Los Angeles International
21 Airport, Unindicted Co-Conspirator C did not declare to CBP the
22 commercial merchandise in her possession, namely drugs purchased
23 in India.

24 OVERT ACT #20: On or about March 12, 2008, defendant
25 signed wire transfer instructions authorizing a payment of
26 \$21,000.00 to Arihant Chemist, Pune, India for the purchase of
27 drugs brought into the United States by Unindicted Co-Conspirator
28 C from India.

1 OVERT ACT #21: On or about April 4, 2008, Unindicted
2 Co-Conspirator A purchased drugs in Manila, Philippines.

3 OVERT ACT #22: On or about April 5, 2008, after
4 arriving via commercial airliner at Los Angeles International
5 Airport, Unindicted Co-Conspirator A did not declare to CBP the
6 commercial merchandise in her possession, namely drugs purchased
7 in the Philippines.

8 OVERT ACT #23: In or about April 2008, in Upland,
9 California, defendant received the drugs purchased by Unindicted
10 Co-Conspirator A in the Philippines.

11 OVERT ACT #24: On or about May 28, 2008, in Upland,
12 California, defendant asked Unindicted Co-Conspirator B to ask
13 Unindicted Co-Conspirator C to purchase unapproved drugs in
14 India. Defendant asked Unindicted Co-Conspirator B to tell
15 Unindicted Co-Conspirator C that the request came from Unindicted
16 Co-Conspirator B, and not defendant.

17 OVERT ACT #25: On or about June 19, 2008, Unindicted
18 Co-Conspirator C traveled from Los Angeles International Airport
19 to London, England.

20 OVERT ACT #26: On or about June 21, 2008, in Upland,
21 California, at the request and on behalf of defendant, Unindicted
22 Co-Conspirator B prepared a check drawn on defendant's medical
23 practice's bank account made out to Unindicted Co-Conspirator C
24 to pay for Unindicted Co-Conspirator C's travel expenses in
25 connection with a trip to India.

26 OVERT ACT #27: On or about July 3, 2008, after arriving
27 via commercial airliner at Los Angeles International Airport,
28 Unindicted Co-Conspirator C did not declare to CBP the commercial

1 merchandise in her possession, namely unapproved drugs purchased
2 in India on defendant's behalf for use in his medical practice.

3 OVERT ACT #28: On or about July 7, 2008, in Upland,
4 California, defendant directed Unindicted Co-Conspirator B to
5 provide to Unindicted Co-Conspirator C the check Unindicted Co-
6 Conspirator B prepared on or about June 21, 2008.

COUNTS TWO AND THREE

[21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1)]

24. On or about the dates listed below, in San Bernardino County, within the Central District of California, defendant VINOD CHANDRASHEKM PATWARDHAN, with the intent to defraud and mislead, introduced and delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce of, the items specified below in each Count, each of which were drugs within the meaning of the FD&C Act, which were misbranded in one or more of the following ways:

A. Within the meaning of Title 21, United States Code, Section 352(c), in that their label or labeling was not in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use; and

B. Within the meaning of Title 21, United States Code, Section 352(f)(1), in that their labeling failed to bear adequate directions for use:

COUNT	DATE	ITEM
TWO	11/19/07	23 vials of Farmorubicina 50 mg from Honduras to Upland, California
THREE	3/2/08	100 vials of Docetax 80mg from India to Upland, California

COUNTS FOUR AND FIVE

[18 U.S.C. § 545]

25. On or about the dates listed below, in Los Angeles County, within the Central District of California, defendant VINOD CHANDRASHEKM PATWARDHAN fraudulently and knowingly imported and brought into the United States merchandise, namely, drugs purchased in India, contrary to law.

COUNT	DATE
FOUR	11/5/05
FIVE	1/3/07

COUNT SIX

[18 U.S.C. § 545; 18 U.S.C. §§ 2(a), (b)]

26. On or about November 19, 2007, in San Bernardino County, within the Central District of California, defendant VINOD CHANDRASHEKM PATWARDHAN knowingly and intentionally aided, abetted, counseled, commanded, induced, procured, and caused the fraudulent and knowing importation and bringing into the United States of merchandise, namely, drugs purchased in Honduras, contrary to law.

COUNT SEVEN

[18 U.S.C. § 982(a)(2)(B); 21 U.S.C. § 853(p)]

27. The allegations of paragraphs 21 through 23 and 25 through 26 are realleged and incorporated by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, § 982(a)(2)(B).

28. Pursuant to Title 18, United States Code, § 982(a)(2)(B) and Title 21, United States Code, § 853(p), if convicted of one or more of the offenses charged in Count One (as it relates to smuggling) and Counts Four through Six, the Court shall order that defendant VINOD CHANDRASHEKM PATWARDHAN shall forfeit to the United States the following:

a. All property, real or personal, that constitutes or is derived from proceeds obtained directly or indirectly as a result of the violations of such offense(s), or conspiracy to commit such offense(s); and

b. A sum of money equal to the total amount of money obtained as a result of each such offense or conspiracy to commit such offense for which the defendant is convicted.

c. Pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b), defendant shall forfeit substitute property, up to the value of the amount described above, if by any act or omission of the defendant, the property described above, or any portion thereof, cannot be located upon the exercise of due diligence; has been transferred, sold to, or deposited with a third party; has been placed beyond the jurisdiction of the court; has been substantially diminished in value; or has been commingled with

other property that cannot be divided without difficulty.

COUNT EIGHT

[18 U.S.C. § 981(a)(1)(C); 28 U.S.C. § 2461(c);
21 U.S.C. § 853(p)]

29. The allegations of paragraphs 21 through 23 are
realleged and incorporated by reference for the purpose of
alleging forfeiture pursuant to Title 18, United States Code,
§ 981(a)(1)(C), Title 28, United States Code, § 2461(c), and
Title 21, United States Code, § 853(p).

30. Pursuant to Title 18, United States Code,
§ 981(a)(1)(C), Title 28, United States Code, § 2461(c), and
Title 21, United States Code, § 853(p), if convicted of the
offense charged in Count One, the Court shall order that
defendant VINOD CHANDRASHEKM PATWARDHAN shall forfeit to the
United States the following:

a. All property, real or personal, that constitutes
or is derived from proceeds obtained directly or indirectly as a
result of a conspiracy to defraud HHS; and

b. A sum of money equal to the total amount of money
obtained as a result of such offense for which the defendant is
convicted.

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1 c. Pursuant to Title 21, United States Code, Section
2 853(p), as incorporated by Title 28, United States Code, Section
3 2461(c), defendant shall forfeit substitute property, up to the
4 value of the amount described above, if by any act or omission of
5 the defendant, the property described above, or any portion
6 thereof, cannot be located upon the exercise of due diligence;
7 has been transferred, sold to, or deposited with a third party;
8 has been placed beyond the jurisdiction of the court; has been
9 substantially diminished in value; or has been commingled with
10 other property that cannot be divided without difficulty.

11
12 A TRUE BILL

13 15/
14 Foreperson

15
16 THOMAS P. O'BRIEN
United States Attorney

17 CHRISTINE C. EWELL
18 Assistant United States Attorney
Chief, Criminal Division

19 
20
21 SHERI PYM
Assistant United States Attorney
Chief, Riverside Office

22 JERRY A. BEHNKE
23 Assistant United States Attorney
Deputy Chief, Riverside Office

24 JOSEPH B. WIDMAN
25 Assistant United States Attorney